UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/351,057	07/12/99	SLON-USAKIEVICZ J	06942/021001

HM12/0731

MARY ROSE SCOZZAFAVA
CLARK & ELBING LLP
176 FEDERAL STREET
BOSTON MA 02110

EXAMINER	
DELACROIX MUIRHEI,C	
ART UNIT	PAPER NUMBER
1614	11

DATE MAILED: 07/31/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/351,057	Applicant(s) DESJARDINS et al.
	Examiner Cybille Delacroix-Muirheid	Art Unit 1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Nov 6, 2000 and June 22, 2001*.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above, claim(s) *2, 4, and 9* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 3, 5-8, and 10-27* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

The following is responsive to Applicant's elections received Nov. 6, 2000 and June 22, 2001.

Applicant's election of gastrin-releasing protein, C=O, n=0 and Bodipy is acknowledged.

Claims 2, 4, 9 are withdrawn from consideration.

Information Disclosure Statement

Applicant's Information Disclosure Statement received Nov. 1, 1999 has been considered. It is noted that page 7 is missing from the file and it is respectfully requested that Applicant submit this page so that the references may be initialed as having been considered.

Submitted herewith is a copy of the 1449.

Oath/Declaration

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: the filing date for 08/504,856 is indicated as "June 20, 1995". The correct filing date appears to be July 20, 1995. Correction is respectfully requested.

Priority

Applicant's claim for priority to grandparent application 08/504,856 is noted. However, A claim can only have one effective filing date. Please see Studiengesellschaft Kahle m.b.H. v. Shell Oil Co., 42 USPQ2d 1674, 1677 (Fed. Cir. 1997). In the instant application, the elected species gastrin-releasing peptide does not have support back to 08/504,856 which was filed July 20, 1995. Since the claim as whole can only have one effective filing date, the claims of the instant application will be treated as having an effective filing date of July 12, 1999. Any intervening art applied in a rejection may be overcome by cancelling the

relevant claim limitations or where appropriate, by submitting an affidavit or declaration under 37 CFR 1.131 to antedate the intervening art.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 10, 11, 17, 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Fluo-GRP™.

Applicant disclosed the existence of a fluorescently labeled gastrin-releasing peptide introduced by the assignee, Advanced Bioconcept Ltd. Please see the paper received Nov. 1, 1999.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly

owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1, 3, 5-8, 10-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over EPA 606 804 ('804) in view of Bunnett et al.

EPA '804 teaches a fluorescent compounds and method of making thereof, wherein said compounds are useful for flow cytometric studies, cell sorting and receptor-labeling experiments, said compound comprising a fluorophore (R1) selected from the group consisting of fluorescein, rhodamine, blue fluorescent and Bodipy™; a carbon=oxygen linkage; and a polypeptide moiety (R), which is disclosed as being a neurotensin analogue. Please refer to the abstract; page 2, lines 11-12; p. 6, lines 47-51; page 7, lines 19-30.

EPA '804 does not disclose that the polypeptide moiety is a gastrin-releasing peptide (GRP) as claimed by Applicant, yet the Examiner turns to the Bunnett et al. patent which teaches cyanine labeled GRP which may be used in receptor localization or flow analysis and cell sorting. Please see abstract; page 733, second column, first full paragraph to page 734, line 3.

It would have been obvious to one of ordinary skill in the art to modify the compound of EPA '804 by linking the cyanine labeled GRP of Bunnett et al. to the fluorophores, namely Bodipy™, of EPA '804 not only because fluorescently labeled GRP is known in the art, as shown by Bunnett et al., but also because EPA '804 **raises expectation of success** by disclosing that conjugating the neurotensin peptide to the fluorophore through a carbon=oxygen bond results in a compound that **retains** the "pharmacological" or functional properties that are found in the native peptide, thus producing a compound that is a **non-t xic, highly sensitive marker f r identifying receptors f interest**. Kindly refer to p. 6, lines 52-58 to p. 7, lines 1-9. Thus, such a modification would have been motivated by the reasoned expectation of

successfully producing GRP having (1) retained biological activity and (2) high sensitivity for identification of receptors of interest.

Finally, with respect to the method of preparing the claimed compound, it appears that EPA '804 (1) determines the peptide exhibiting biological activity which is to be labeled and (2) then reacts the light emitting moiety with the peptide. It is the Examiner's position that Applicant's claims are not only met by EPA '804 but are obvious in view of the fact that it is held that "transposition of the varying steps... of a process...does not avoid obviousness where the processes are substantially identical or equivalent in terms of function, manner and result". Please refer to *General Foods Corp. V. Perk Foods Co.*, 157 USPQ 35.

Concerning claim 20, which is drawn to the pharmacological salts of GRP, modification of GRP into pharmacological salts is obvious and well within the capability of the skilled artisan.

Conclusion

Claims 1, 3, 5-8, 10-27 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

CDM

July 26, 2001

Cybille Delacroix-Muirheid
Patent Examiner Group 1600